

REMARKS

Claims 1 to 9 and 12 to 16 are in the application. Claims 12 to 16 have been added. Claims 1, 7 and 9 have been amended. Support for the newly added claims and amendments lie in the originally filed claims, in the working examples, and in the specification on Page 3, line 43, Page 4, lines 5 to 10, Page 29, lines 7 to 43, and Page 30, lines 1 to 14. The amendment to claim 7 corrects minor typographical errors. No new matter is believed added.

A supplemental IDS and 1449 form accompany this response.

**Rejection under 35 USC 112**

Claims 1 to 9 are rejected under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner comments that Claim 1 is in error as the formula contains a proviso with the term “m” which is indefinite. The proviso was in the originally filed claims to distinguish over the claims of USSN 10/492,698. The claim has been amended to better clarify and distinctly claim the invention.

Claim 9 is rejected under 35 USC 112, 1rst paragraph as failing to comply with the written description requirement because the specification and application while being enabled for treating a disease state mediated by p38 kinase activity or mediated by cytokines, such as psoriasis and rheumatoid arthritis does not enable one skilled in the art to which it pertains or with which it is most nearly connect, to practice the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

With respect to the state of the art at the time the application was filed, the signaling pathway of p38 kinase had been extensively studied. Applicants enclose for the Examiner’s review an article on signaling cascades in inflammatory diseases (see Herlaar, E. et al., Molecular Med Today (1999), Vol. 5, 439-447). This article and several additional articles on p38 kinase inhibitors which also accompany this response detail the linkage to a number of acute and chronic inflammatory diseases, such as RA, osteoarthritis, inflammatory bowel disease, toxic shock syndrome, septic shock, asthma, chronic obstructive pulmonary disease (COPD), acute respiratory

distress syndrome (ARDS), and osteoporosis. The skilled artisan would also have available many more articles describing the role of the pro-inflammatory cytokine in the diseases enumerated herein.

The Examiner in Point 7 (page 6 of the office action), states that the specification has “no working examples”. Applicants respectfully disagree. While there is no legal requirement to provide actual data in a specification, the present application does in fact have such. In the fluorescence anisotropy binding assay (page 35, lines 10 to 22, and page 36, lines 1 to 22) which determines *in vitro* p38 activity, the Results section on page 36, lines 20 to 22 clearly indicates that compounds of the working Examples were in fact tested and found active in this assay.

The specification further provides sufficient information on how to make and how to use the compounds as claimed herein. The specification on Page 21, lines 22 to 43 through Page 31, line 22 describes how to formulate, how to dose, and how to administer the compounds of Formula (I). Therefore, Applicants believe that the specification is sufficiently enabled and would not require undue experimentation to practice the invention.

While Applicants do not agree with the Examiner that Claim 9 as written does not specify the many possible diseases mediated by p38 kinase activity, Applicants have amended Claim 9 to include the recitation of diseases listed in the specification on pages 29 and 30. A narrower genus of diseases appears in newly added claim 13. Consequently, it is believed that this part of the rejection has been rendered moot.

In view of the amendments and remarks, reconsideration and withdrawal of the rejection or objection to the claims under 35 USC §112 is respectfully requested.

**Rejection for Obviousness type Double Patenting**

Claims 1 to 11 are provisionally rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1 to 13, 16- 20 of copending application, USSN 10/492,698.

The provisional rejection of claims 1 to 11 under obvious-type double patenting over claims 1 to 13 and 16 to 20 of copending application, USSN 10/492,698 is overcome in view of the terminal disclaimer submitted herewith.

As no additional outstanding rejections are in the application, a notice of allowance of the claims in this application is respectfully requested.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case, the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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